(i) SECTION B Premarket Notification [510(k)] Summary

DEC 2 3 2002

"This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92."

"The assigned 510(k) number is: K022690 .

Company: ABX Diagnostics
34 Bunsen Drive
Irvine CA92618
USA
Phone: (949)-453-0500
Fax: (949)-453-0600
Contact Person: Ian Giles
Date Prepared: May 20, 2002

Trade Name: Paros CRP

Common Name: In Vitro Diagnostic C-Reactive Protein Immunological Test System

Classification Name: C-Reactive Protein Immunological Test System

Device Classification: Class II

Regulation Number: 21 CFR (866.5270)

Substantial Equivalence:

The Paros CRP is substantially equivalent to the following devices:

- ABX / Horiba ™ MICROS CRP (K002646 October 2000)
- Beckman Coulter Immage IMMUNOCHEMISTRY SYSTEM (K981638 June 1998).

Description:

The Paros CRP is a benchtop C-Reactive Protein Immunological Test System. It is a single parameter instrument (CRP only), with the ability to measure CRP on Whole Blood and Serum samples *in-vitro*. It employs the same measurement principles as the CRP measurement module of the ABX / Horiba ™MICROS CRP (K002646, October 2000). The Paros CRP does not have a cell counting module.

The CRP levels are measured in patients by reacting anti-CRP antibody coated latex particles with lyzed blood, and determining the rate of the turbidimetric reaction in the near infrared spectrum.

Indications for Use:

The indications for use of the Paros CRP are for aiding in diagnosis and monitoring of inflammatory diseases. The primary utility is for screening for the presence of inflammatory disease, by measuring CRP on anti-coagulated whole blood samples, and thus eliminating the requirement for sample centrifugation. CRP measurement on serum samples is also possible.

Discussion of Performance Data Summary:

The determination of substantial equivalence is based on precision, linearity, stability and carry-over studies as well as an inter-procedural correlation study.

The data presented in this 510K Pre-market Notification demonstrate good precision as assessed by NCCLS EP5-A. *Total Imprecision* ranged from between 0 and 2.6 CV%.

Accuracy / bias assessment (NCCLS EP 9-A) showed no evidence of significant bias. Good correlation was demonstrated between the Paros CRP and the Beckman Immage for Whole Blood (R^2=0.99). Similarly, the correlation for Serum samples between the Paros CRP and the Beckman Immage was excellent (R^2=0.98). For Whole blood samples, the linear regression formula of the trend line was Y=0.92X + 0.03. A comparison of the serum results showed linear regression trend line formula of: Y=0.95X.

Linearity assessment data supports a Whole Blood CRP linearity claim from 0.2 to 10 mg/dl; and for Serum samples, a linearity range between 0.2 and 7 mg / dl is supported.

The data shows linearity across the tested range for Whole Blood (Paros CRP result = 1.05 X Expected Target CRP value) R^2 = 0.99; and serum: (Paros CRP result = 0.9X Expected Target CRP value) R^2 = 0.98.

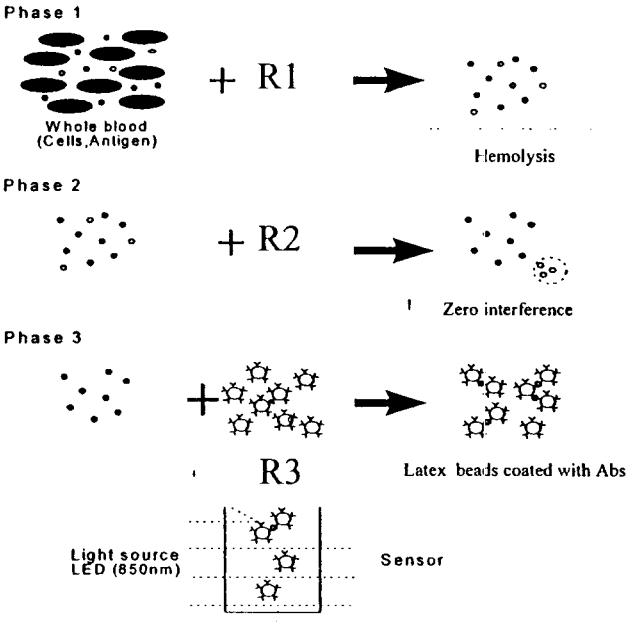
The *Sample Stability Study* showed reproducibility of results over the entire 72 hour assessment period. At a level of 0.2 mg / dl, the % difference in results can be attributed to the fact that there is a single decimal point on the CRP result, and to the level of CRP testing. All other results showed <10% deviation from the baseline measurement.

There was Zero % *Carry-over* in this study.

Potential Interfering Clinical Conditions were investigated. Samples with hyperbilirubinemia, hemolysis, hypergammaglobulinemia, and hyperlipemia were included in the bias assessment study. Pathological diagnoses in the bias assessment study included: Multiple Myeloma, Rheumatoid Arthritis, Giant Cell Arteritis, Polymyalgia Rheumatica, Polymyositis, non-specific arthropathies, and somatic carcinomas.

Prepared By:
Dr Ian Giles ABX Diagnostics

The principles of immuno-turbidimetry on the MICROS CRP and PAROS CRP are summarized below:



Principles of CRP Measurement on Whole Blood.

Phase 1 : Hemolysis, using reagent R1 ; R1 contains saponin as active principle.

Phase 2 : Incubation of the hemolysate with R2, which inhibits potential interference during the incubation with the specific R3 reagent.

Phase 3 : Incubation with latex beads coated with anti-CRP antibodies.
The recognition of CRP by anti-CRP antibodies induces bead aggregation. This increases the turbidity (opacity) of the incubation medium. The rate of change in turbidity is measured by using a light source (850nm LED) and an optical sensor.

1. MICROS CRP SPECIFICATIONS

MICROS CRP technical specifications are summarized in Table 3.

MICROS CRP SPECIFICATIONS	
Parameters	
CBC/DIFF Mode	18 parameters (16 for the US) with graphics for RBC, PLT and WBC populations RBC, HGB, HCT, MCH, MCHC, RDW PLT, MPV, PDW*, THT* LYM, MON, NEU (% and #)
CRP Mode	19 parameters (17 for USA) with graphics for RBC, PLT and WBC populations RBC, HGB, HCT, MCH, MCHC, RDW PLT, MPV, PDW*, THT* LYM, MON, NEU (% and #) CRP
Reagents	
CBC/DIFF Mode	<u>Three reagents</u> : ABX MINIDIL LMG, ABX ALPHALYSE, ABX MINICLEAN
CRP Mode	<u>Six reagents</u> : ABX MINIDIL LMG, ABX ALPHALYSE, ABX MINICLEAN CRP-100 (CRP-R1, CRP-R2, CRP-R3)
Quality Control	Calibrator (Hematology) : Minocal Control Blood : Minotrol 16 (L, H, M) CRP Calibrator : CRPCAL CRP Control : CRPTROL (L, H)
Principles of Measurement	Spectrophotometry (HGB) Impedance (CBC/DIFF)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 2 3 2002

Horiba, Ltd.
c/o Dr. Ian Giles
ABX Scientific Affairs Manager
ABX Diagnostics
34 Bunsen Drive
Irvine, CA 92618

Re: k022690
Trade/Device Name: Paros CRP
Regulation Number: 21 CFR 866.5270
Regulation Name: C-reactive protein immunological test system
Regulatory Class: Class II
Product Code: DCN
Dated: November 20, 2002
Received: November 22, 2002

Dear Dr. Giles:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K 022690

Device Name: Paros CRP

Indications For Use: Indications for Use:

The indications for use of the Paros CRP are for aiding in diagnosis and monitoring of inflammatory diseases. The primary utility is for screening for the presence of inflammatory disease, by measuring CRP on anti-coagulated whole blood samples, and thus eliminating the requirement for sample centrifugation. CRP measurement on serum samples is also possible.

A C-reactive protein immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the C-reactive protein in serum and other body fluids. Measurement of C-reactive protein, aids in evaluation of the amount of inflammatory injury to body tissues.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use

(Per 21 CFR 801.109) (Optional Format 1-2-96)

J. P. Reeve for J. Bautista

(Division Sign-Off)

Division of Clinical Laboratory Devices

510(k) Number K022690